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Title

A comparison between independent nurse prescribing and patient group directions in the safety and appropriateness of medication provision in United Kingdom sexual health services: a mixed methods study

Abstract

Background:

United Kingdom legislation allows nurses to autonomously provide medications as independent nurse prescribers or using patient group directions. Evidence of medication safety and appropriateness is limited. We compared nurse prescribers and patient group direction users in terms of prevalence, types and severity of medication provision errors.

Methods:

Objectives: Compare safety and appropriateness of medication provision between nurse prescribers and patient group direction users

Design: Mixed methods: clinical notes review and nurse-patient consultation observations.

Setting: Five United Kingdom sexual health services.

Selection criteria: 'Clinical notes review' included a random selection of nurse-patient consultations July-December 2015, 743 consultations managed by nurse prescribers and 939 consultations by patient group direction users. 'Observation study' involved 15 nurse prescriber and 15 patient group direction user nurse-patient medication consultations. Patients aged under 16 or non-English speaking were excluded.

Measurements: Medication safety/appropriateness was compared between nurse prescribers and patient group direction users. Medication provision errors were categorised and assigned severity ratings. The Medication Appropriateness Index and the Prescribing Framework were used to assess medication provision.

Results:

Of 1,682 clinical notes (nurse prescribers=743, 44%; patient group directions=939, 56%), 879 involved the provision of 1,357 medications (nurse prescribers=399, 54%; patient group directions=480, 51%). The overall error rate was 8.5% (1,844 errors from a potential 21,738 errors), predominantly related to documentation omissions. Nurse prescribers were more likely to make an error compared to patient group directions users (error rates 9% versus 8%, respectively; $p=0.001$); most were 'minor' (nurse prescribers=489, 56%; patient group directions=602, 62%). Both nurse prescribers and patient group direction users made safe medication decisions ($n=1,640$ of 1,682 patient care episodes, 98%); however, patient group directions users worked outside patient group directions restrictions in 39 (8%) of consultations. In 101 consultations, medication was indicated but not documented as offered/provided.

From 30 observed consultations assessed against the Prescribing Framework, nurse prescribers' and patient group directions users' clinical practice were comparable (maximum score 46: nurse prescribers=44.7; patient group direction=45.4, $p=0.41$).

Conclusion

Sexual health nurse prescribers and patient group direction users provided safe and therapeutically appropriate medication. Improvements in clinical documentation are recommended. Moreover, patient group directions users should be encouraged to adhere to

patient group directions' governance restrictions, such as through regular training, audits and staff updates.

Contribution of paper

What is already known about the topic?

- Legislation allowing nurses to independently provide medication is expanding throughout the world. Despite existing evidence demonstrating that nurses do so safely, some specialties, organisations and countries have reservations.
- Existing evidence on nurse provision of medications is predominantly around independent nurses prescribing; there is little evidence exploring safety of patient group direction use.
- Large studies of prescribing safety and appropriateness focus predominantly on medical doctors. While a small number of nurses have been included in these studies and have been shown to be as safe as doctors, there is limited evidence regarding how safe nurses are at independently providing medication.

What this paper adds

- Both independent nurse prescribers and nurses using patient group directions working in sexual health provided medications safely and appropriately despite significant differences in training and governance. Nevertheless, patient group direction users need to be mindful of the restrictions associated with specific patient group directions.
- The importance of comprehensive clinical documentation was clearly demonstrated as many medication provision errors attracted increased severity ratings based on documentation omissions.
- Further evidence is presented that nurses use their medication provision capabilities safely and responsibly. This has implications for other clinical services and countries considering introducing similar medication provision powers for non-medical healthcare professionals.

Keywords

- Health services research
- Medication safety
- Medication management
- Nurse/ non-medical prescribing
- Prescribing errors/ severity
- Sexual health

Introduction

Internationally, independent nurse prescribing has been introduced in a variety of countries including Australia, Canada, Ireland, Spain, New Zealand, Norway, South Africa, Sweden, the Netherlands, United Kingdom, United States of America (Kroezen et al., 2011; Gielen et al., 2014), Israel and Poland. China are also considering the adoption of this role by nurses (Ling et al., 2018). The freedom to prescribe independently varies considerably between

countries; 'non-medical prescribing' can therefore range internationally from access to a limited formulary to a wide and flexible authority (Gielen et al., 2014). Nurses in Australia, Canada and the United Kingdom are also able to use medication group directions to deliver medicines to patients. Despite this international increase in nurses autonomously providing medications, concerns are common regarding nurses' ability to do so safely and appropriately (Kroezen et al., 2011; Gielen et al., 2014).

The United Kingdom is considered world-leading with regards to scope of practice for medication provision (Kroezen et al., 2012). Since the introduction of medication legislation in the United Kingdom (*Medicines Act, 1968*, c.67), prescribing was predominantly restricted to medical doctors. However, since 2001 nurses have been increasingly afforded the power to prescribe (Great Britain. *Health & Social Care Act 2001*; Department of Health, 2006; *The Human Medicines Regulations 2012* (Statutory Instrument 2012/1916); Kroezen et al., 2014). The capability to prescribe requires nurses to be responsible for the assessment, diagnosis and decisions about the clinical management of patients' health-related conditions (Department of Health, 2001). Becoming an independent nurse prescriber requires individual professionals to obtain a university-based qualification, six months in duration, at postgraduate degree or master's level and then register with the United Kingdom Nursing and Midwifery Council (2006; Department of Health, 2006).

In 2000, the Department of Health (2000) also introduced patient group directions, which permit appropriately trained healthcare professionals to independently supply and/ or administer specific medication for patients who present with pre-determined medication requirements. In contrast to prescribing, patient group directions are less flexible documents that allow pre-specified groups of locally trained and assessed healthcare professionals to autonomously provide medication in specific circumstances. As supplying/administering medication using a patient group direction is not prescribing, the term 'medication provision' is used here to denote both patient group direction and independent nurse prescribers' autonomous provision of medications.

Safety and appropriateness of medication provision

Medication provision errors are the third most common patient safety incident reported in England and Wales, after accidents and implementation of care/ monitoring issues (National Health Service Improvement, 2017). The most common medication incidents include wrong dose, omitted or delayed drugs, wrong medication supplied (National Patient Safety Agency, 2012; Seden et al., 2013), incomplete or inaccurate information on prescriptions and incorrect timing of doses (Avery et al., 2012). Although focusing on medical prescribers, large-scale medication safety studies have explored the incidence and nature of prescribing errors in general practice clinical notes (Avery et al., 2012) and inpatient prescribing charts (Dornan et al., 2009; Seden et al., 2013) or inpatient/ discharge medication orders (Franklin et al., 2011) within hospitals in England. Error rates across these specific studies ranged between 8.9% of medication orders (Dornan et al., 2009) to 43.8% (Seden et al., 2013) of prescribing charts, with varying degrees of severity across various healthcare professional groups. The small number of nurse prescribers' prescriptions reviewed in such studies suggests nurse prescribers to be as comparably safe as their medical consultant colleagues (Dornan et al., 2009; Avery et al., 2012; Seden et al., 2013).

The ability to independently deliver medication has the potential to improve prescribing safety as it avoids interruptions in consultations (Courtenay et al., 2009b; Avery et al., 2012; Wilkinson et al., 2014) and nurses can take responsibility and accountability for their own

medication decisions (Bradley et al., 2005; Bradley et al., 2007; Bradley and Nolan, 2007; Pontin and Jones, 2007; Stenner and Courtenay, 2008; Courtenay et al., 2009b; Price et al. 2012; Schirle and McCabe, 2016). Some studies have, however, identified cases of medication provision errors by nurses including errors in accuracy and completeness of prescriptions (Carey et al., 2008); incomplete documentation within clinical records (Latter et al., 2007a; Black, 2012; Wilkinson et al., 2014); lack of documented diagnosis, management plans, follow-up requirements and specific prescription details (Latter et al., 2007a); lack of enquiry about medical histories, concurrent medications, allergies and over-the-counter medicines (Latter et al., 2007a; Courtenay et al., 2009a; Courtenay et al., 2009b). While these studies all address different components of medication governance, the issues raised provide an extensive range of prescribing error categorisations that require further exploration. Moreover, while nurses deliver appropriate medication choices (Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012), issues have been identified in relation to educating patients on how to take medication (Latter et al., 2007b; Latter et al., 2012), the duration of regimens (Latter et al., 2012; Naughton et al., 2012), medicine/disease interactions (Naughton et al., 2012) and ensuring cost-effective prescribing (Latter et al., 2012).

Existing evidence surrounding patient group direction application within clinical practice is scarce; however, patient group directions have been reported to support safe appropriate medication provision (Brooks et al., 2003; Baileff, 2007; Williams and Knox, 2011). Nevertheless, there have been reports of patient group direction use outside of the patient group directions' scope of practice (Miles et al., 2001; Black and Dawood, 2013).

Despite the exponential growth of nurses delivering medication, in the United Kingdom and internationally, there is only limited evidence that has specifically explored safety and appropriateness of medicines provision by nurses. Furthermore, despite the adoption of increasingly autonomous roles by nurses working in sexual health (Department of Health, 2013) and sexual health being an area in which both nurse prescribers and patient group directions are routinely used (Miles et al, 2001; Black, 2012) no research has explored the safety and appropriateness of medicines provision by nurses within this setting.

The aim of this study was to compare nurses' use of independent prescribing and patient group directions with regards to the quality of care provision and the prevalence, types and severity of medication provision errors. This was intended to help guide policymakers, managers and clinical staff to determine whether independent nurse prescribing and/ or patient group directions are safer or more appropriate for their clinical area or practice.

Methods

Design

The findings reported in this paper formed part of a larger mixed methods study comparing nurse prescribers and patient group directions use in sexual health from the perspectives of clinical application, patient experience and costs. This paper presents findings from a review of clinical notes and structured observations; other findings are presented elsewhere (Black et al., 2020a; Black et al., 2020b).

Setting

Five urban outpatient sexual health services across the United Kingdom including three in England, one in Wales and one in Scotland. Sites were purposively sampled to reflect tertiary level complex specialist management of sexual health patient presentations where nurses used prescribing and/ or patient group directions. Three used electronic documentation for clinical notes and medication provision, and two used paper-based records.

Data collection methods

Clinical notes review

A template was used to extract data from patient clinical records. Data included patients' demographic details, reason for presentation, existing medical conditions, concurrent medication, pregnancy risk, diagnosis and medication provided. This information was anonymised and recorded in a Microsoft Access® database.

Medication data from the clinical notes were then further scrutinised to (i) assess the completeness of documentation of medications delivered with regards to patient's name/ details; name of drug/ formulation; strength (if applicable); dosage; frequency; quantity/ duration; whether signed and dated (British National Formulary, 2016); and whether medication was delivered via patient group directions (if applicable) in the clinical records (National Institute for Health and Care Excellence, 2013) (ii) categorise medication provision errors and determine their potential severity using an existing validated tool (Dean and Barber, 1999); (iii) assess the appropriateness of medication delivered using the Medication Appropriateness Index (Hanlon et al., 1992); (iv) explore the appropriateness of patient group direction documents in clinical practice, and (v) evaluate the appropriateness of decisions not to provide medications.

The clinical notes of patients attending each of the five clinics between 1 July 2015 and 31 December 2015 and were predominantly managed by nurse prescribers or patient group direction users were reviewed. The clinical notes were randomly selected for inclusion from patient attendance lists. Each patient presentation was allocated a random number using Microsoft Excel®, sorted into ascending numerical order and data from the corresponding clinical notes extracted until that site's quota was obtained. Site quotas were stratified based on the number of nurse prescribers or patient group direction users at that site (e.g. Site 1 had 39% of nurse prescribers; therefore, we aimed to obtain 39% of the nurse prescriber sample size at this site). Based on previous work (Black, 2012) to test for a difference in prescribing rates of 90% and 98% with 99% power at the 5% level of significance required 344 patients (clinical notes) per group (nurse prescribers or patient group directions). Data were collected for four patient groups: patients for whom (1) nurse prescriber provided medication, (2) nurse prescriber did not provide medication, (3) patient group direction user provided medication, and (4) patient group direction user did not provide medication.

Definition of a medication provision error

Medication provision errors were defined "*when, as a result of a prescribing decision or prescription-writing process, there is...the risk of harm when compared to generally accepted practice*" (Dean et al., 2000). Based on this definition, the literature reviewed, and the research tools used in this study, 'prescribing processes' were regarded to go beyond the documented prescription and consider the full clinical assessment of the patient prior to, during and after medication provision. Where an error category was identified, the potential

of that error occurring across all cases of medication provision in this study was determined to provide the denominators for error rate calculations. (For example, we found that (i) nurse prescribers provided 620 medications overall; therefore had the potential to provide inaccurate/ undocumented 'route of medication administration' 620 times; (ii) patient group direction users provided 256 medications to female patients, therefore had to consider pregnancy risk assessments in 256 of 737 medications provided, see Table 1). Consequently, there was a total of 21,738 potential medication errors determined that could occur within this study (nurse prescribers=9,586; patient group directions=12,152, see Table 2); these figures are used as the denominators for overall medication provision error rates unless otherwise stated).

Measure of medication provision error severity

The severity of medication provision errors was assessed using Dean and Barber's (1999) validated, reliable scoring tool, which uses a visual analogue scale between 0-10 to assess severity in which zero refers to no potential effect, and 10 an error that would result in death. Scores zero to 2.9 are considered minor, 3.0 to 6.9 are moderate, and 7 and over are severe (Dean and Barber, 1999). Five judges (one expert research pharmacist, two consultant sexual health physicians and two experienced sexual health nurse prescribers) independently scored each error, and the mean score across the five judges calculated to define the severity of each error. Worse case scenarios were put forward to the judges wherever ambiguities existed within the clinical documentation (e.g. if the documentation referred to 'anti-hypertensive', rather than a specific drug, the most serious potential drug interaction with an anti-hypertensive was provided in the description of the error).

Measure of medication appropriateness

The appropriateness of clinical practice was assessed against relevant local and national prescribing and sexual health guidelines, governance and legislation (e.g. British Association of Sexual Health & HIV, 2016; British HIV Association, 2016; Faculty of Sexual & Reproductive Health, 2016). The appropriateness of patient group direction use was assessed using local documents to determine whether medication provision was within the scope of the patient group directions. Practice safety assessments were based on the severity of medication provision errors/ omissions.

The Medication Appropriateness Index was also used to assess appropriateness of medicines delivered. This uses 10 questions (Online Box 1), typically each with four responses: 'indicated', 'intermediate', 'not indicated' or 'not sufficient information' (Hanlon et al., 1992). Analysis was undertaken for each individual medication provided. Where a patient was given more than one drug, multiple Medication Appropriateness Index assessments were undertaken for that patient. A weighted scoring system (Online Box 1) is used to determine the level of inappropriate medication provision, ranging from 0 (all appropriate) to 18 (all inappropriate). A score closer to '0' indicates more appropriate medication use (Hanlon et al., 1992).

Consultation observations

A structured observation schedule, based on the Royal Pharmaceutical Society prescribing competency framework (Royal Pharmaceutical Society 2016) was used to observe and assess nurse prescribers and patient group direction users' competence during patient consultations. An earlier edition of this framework (National Prescribing Centre 2001) has been used previously by researchers (Latter 2005, Courtenay et al 2009a, Courtenay 2009b) to assess the prescribing competence of nurse prescribers. The Royal Pharmaceutical

Society prescribing competency framework (RPS 2016) comprises two domains centred on the 'Patient', these are 'The consultation' (six competencies) and 'Prescribing governance' (four competencies). The six 'consultation' competencies (and their 46 sub-competencies) were used in our study. Consultations were audio-recorded, transcribed verbatim and the observation schedule and transcripts assessed against all of the 46 sub-competencies. Observations took place between June 2016 and February 2017. All entries were anonymised.

Participants and recruitment

Both nurse prescriber/ patient group direction nurses and patients were recruited to participate in the observational study.

Nurse recruitment

We invited nurses within each of the five services who delivered patient medicines using either independent nurse prescribing or patient group directions to participate in the study. We aimed for a total of 30 medication consultations (i.e. five consultations from three different nurse prescribers and three patient group direction users) from each of the five sites, based on study resources.

Patient recruitment

Patient inclusion criteria were that they were aged over 16 years with a good understanding of English and did not present with vulnerability issues (e.g. safeguarding concerns, sexual assault, etc.). Nurses who agreed to participate invited eligible patients to take part. If patients agreed to participate, the researcher (Adam Black) obtained the patient's written consent to observe and audio-record the consultation.

Data analysis

Clinical notes review

Data were analysed using descriptive and inferential statistics supported by the Statistical Package for Social Sciences version 24.0, Microsoft Access® and Microsoft Excel®. Descriptive statistics (means, standard deviation, range, counts and percentages) were used to summarise characteristics of sites, nurses, patients and consultations with reference to age, ethnic origin, diagnosis, medicines provided, appropriateness and safety in medication provision and clinical practice. Inferential statistical tests applied relied on data meeting the relevant tests' assumptions for their use. The Chi-squared (χ^2 , degrees of freedom(df), p) or Fisher's Exact test (if any expected frequency, calculated using the marginal column, row and total counts, was less than 5) was used to determine any statistically significant differences between nurse prescribers and patient group direction users' medication practice with regards to (i) completeness of documentation for medications delivered, (ii) frequency of medication provision errors and their severity, and (iii) overall safety and appropriateness of practice. The independent two samples t-test was used to compare the weighted mean Medication Appropriateness Index scores between nurse prescribers and patient group direction users.

Medication provision error/ omission categorisation and severity

Dornan et al.'s (2009) list of prescribing error categories initially guided categorisation of medication provision errors. The researcher (Adam Black) discussed all medication provision error categories with an experienced senior nurse at each site, and consensus achieved in all cases.

Consultation observations

Adam Black (an experienced senior sexual health nurse and nurse prescriber) rated the various aspects of the consultation's audio-recording and transcript against the six consultation competencies and their 46 sub-competencies using the ratings 'Observed', 'Implied', 'Not observed', 'Not applicable' (see Table 5). Molly Courtenay (an expert in non-medical prescribing research) independently checked four transcripts (27%) and agreed with Adam's assessments. The current sexual health clinical guidelines (British Association of Sexual Health & HIV, 2016; British HIV Association, 2016; Faculty of Sexual & Reproductive Health, 2016) were used to determine the appropriateness of medication choices within the consultations observed. The Mann-Whitney two independent samples U-test was used to compare the prescribing framework score (out of 46) between nurse prescribers and patient group direction users.

Statistical hypothesis testing

A type I error (α) of <0.05 was used to reject the null hypothesis (e.g. $\mu_1 = \mu_2$).

Informed consent & ethical approval

Observational study participants provided written consent prior to their consultations being observed by the researcher. Written consent was not obtained from patients for the care episodes examined for the clinical notes review as patient and staff data were anonymised. Research Ethics Committee approval was obtained from Wales Research Ethics Committee 4 (Reference 15/WA/0120).

Results

A total of 95 nurses across the five sites were found to use independent nurse prescribing (n=28) or patient group directions (n=67).

Clinical notes review

The clinical records review included 1,682 patient presentations (nurse prescribers=743, patient group directions=939); 879 had medication delivered (nurse prescribers=399, 53.7%, patient group directions=480, 51.1%). Over half (n=859, 51.1%) of the patient presentations reviewed were those of female patients. Overall, patients' mean age was 30 years, 73.3% (n=1,232) were 'White' and 68.1% (n=1,145) were heterosexual (see Online Table A). A total of 1,357 drug items were provided (nurse prescribers=620; patient group directions=737), with antibiotics the most common therapeutic group (n=486, 35.8%; Table 1).

With regards to the completeness of documentation, the medicine name was clearly documented on all but one record. Medication dose, route, frequency, duration and the

signature of the medication provider were less consistently recorded (see Online Table B). Patient group directions users were more likely to document all six components of the medication details compared to nurse prescribers (85.5% vs. 82.5% respectively, $\chi^2 = 13.00$, 1df, $p < 0.001$).

Medication provision errors

The clinical notes review identified 1,844 individual medication provision errors from a total of 21,738 potential errors (overall error rate= 8.5%). Nurse prescribers were more likely to make an error than patient group directions users (9.2% vs. 7.9% respectively; $\chi^2 = 10.42$, 1df, $p = 0.001$). Twelve of the 17 error categories related to documentation omissions (Table 2). The majority of errors were considered to be 'minor' (nurse prescribers=489, 55.6% of errors made; patient group directions= 602, 62.4%); however, errors made by nurse prescribers were more likely to be categorised as 'moderate' (percentage of errors: 44.1% vs. 37.4%, association of severity category with nurse prescribers/ patient group directions Fisher's Exact Test = 8.81, $p = 0.007$; Table 3). Four errors (nurse prescribers=2; patient group directions=2) classed as potentially 'severe' (Online Box 2). There was no evidence of any patient harm based on subsequent documentation.

Medication appropriateness

Medication appropriateness index

Across the 1,357 Medication Appropriate Index assessments, both nurse prescribers and patient group directions users consistently provided appropriate medication choices (Table 4). Overall, medication was indicated and likely to be therapeutically effective for 1,336 of 1,357 (98.5%) cases. The most frequent issue identified through the Medication Appropriate Index involved documentation omissions, making it difficult to fully ascertain appropriateness. The main reason for 'inappropriate' categorisations ($n = 100$ of 13,570, 0.7%) related to errors in the documented medication (86 of 100, 86%); e.g. one site's electronic medication template had inaccurate 'dose' and 'directions' details for a metronidazole regimen (resulting in 17 errors each for dose and directions); nevertheless, while the medication documentation was inaccurate, the appropriate medication pre-packs were supplied to patients as intended, in line with local and national guidelines.

The Medication Appropriate Index weighted scoring identified comparable medication appropriateness scoring between nurse prescribers and patient group directions users ($p = 0.30$; independent two samples t-test; Table 4). Based on the Medication Appropriate Index's weighted scoring system, both groups scored very low (scores: nurse prescribers 0.9; patient group directions 0.8 out of 18), demonstrating a high level of appropriate medication provision. Overall, 1,099 of 1,357 (81%) medications scored '0' (i.e. no inappropriate medication provision), with a mean score of 0.9.

Patient group directions appropriateness

Patient group directions were used inappropriately in 72 of 480 (15.0%) patient presentations where medication was delivered by patient group directions users; 39 of 480 (8.1%) cases involved medicines supplied/ administered outside of the patient group direction's scope; however, these medicines were all considered therapeutically appropriate

for the patients' presentations. A further 10 (2.1%) cases involved the patient group directions covering the patient presentation, but a prescription was sought instead with no reason for this documented. The remaining issues predominantly involved documentation omissions.

Appropriateness of not providing medication

From the 1,682 patient presentations reviewed, there were 25 presentations (1.5%) where medication was specifically indicated, for which there was no documentation that it was provided. This mostly related to failure to offer appropriate prophylactic medications (14 of 25, 56.0% or 0.8% overall).

There were a further 101 presentations in which the documentation specified that despite medication being indicated, the nurse appropriately did not provide any, predominantly because the patient declined or wished to wait for results (75 of 101, 74.3%). These cases were deemed as appropriate medication decisions that considered patient preferences and choice.

Overall assessment of safety and appropriateness of medication provision

Across nurse prescribers and patient group directions users (with and without medication provision, n=1,682), most episodes of care were assessed as 'safe and appropriate' (n=1,596, 94.9%). Nurse prescribers were found to provide significantly more appropriate care than patient group directions users (nurse prescribers=714, 96.1%; patient group directions=883, 94.0%; Fisher's Exact Test, $p<0.001$), which was primarily reflects patient group directions being utilised outside their restrictions. There was, however, no significant difference in the safety of care provided between nurse prescribers and patient group direction users (nurse prescribers=713, 96.0%; patient group directions=927, 98.7%: $p=0.55$; Fisher's Exact Test).

Consultation observations

Five nurse prescribers and six patient group direction users participated in the observational study across four sites involving 30 nurse-patient medication consultations. Two-thirds of consultations were with female patients, with a mean age of 27 years. Nurse prescribers managed both heterosexual and homosexual patients; patient group direction users mostly managed heterosexual patients.

Applying the prescribing framework's six competencies (46 sub-competencies: Royal Pharmaceutical Society, 2016) against the 30 consultation observations, nurse prescribers demonstrated a mean score of 44.7 and patient group direction users 45.4 out of 46; with no statistically significant difference (Mann Whitney U=94.5, $p=0.41$; Table 5**Error! Reference source not found.**). Across all observations, nurses frequently demonstrated achievement of competencies in 'Reach a shared decision' and 'Provide information'. Nurses in all consultations were clearly observed taking appropriate histories, clinical assessments and interpreting/ using relevant investigations. Other sub-competencies, while not directly observed, were obviously inherent within nurses' knowledge and skill base. For example, 'Identifies, accesses, and uses reliable and validated sources of information and critically evaluates other information' and 'Stays up-to-date in own area practice and applies the principles of evidence-based practice...' were consistently demonstrated by nurses when making medication decisions based on current local/ national guidance. In these cases,

nurses were not specifically observed undertaking the sub-competency by the researcher (Adam Black), but they were judged to be used as part of their clinical decision making.

In 30 observations there was potential to observe 1,380 competencies, of these only 20 (1.4%) were not observed. These included: 'Guides patients/ carers on how to identify reliable sources of information about their medicines and treatments' and 'Ensures that the patient/ carer knows what to do if there are any concerns about the management of their condition'.

Discussion

Sexual health nurses delivered medications safely and appropriately using independent nurse prescribing and patient group directions. Our findings suggest that sexual health nurse prescribers and patient group direction users are comparable with regards to the quality of care provision. Nurses performed well on taking appropriate clinical histories and assessments, interpreting relevant investigations, understanding the conditions treated and how to effectively manage them. The observations highlighted that both nurse prescribers and patient group direction users consistently listened to patients and sensitively managed their concerns. This is consistent with the findings on nurse prescribers working in the area of diabetes (Courtenay et al., 2009b). Observational data in this study also demonstrated that nurses interacted with patients in a non-judgemental manner, allowing patients to be comfortable talking about their sexual health.

Safety

The most common medication safety issues for both nurse prescribers and patient group direction users related to clinical documentation omissions, usually incomplete information on prescriptions. This concurs with findings from a study exploring general practitioners' prescribing practice (Avery et al., 2012). Although in our study, both groups omitted information on drug dose, routes, administration frequencies and durations, patient group direction users were found to provide significantly more details than nurse prescribers. Findings identified that both nurse prescribers and patient group direction users provided less complete medication documentation than the findings reported in the general nurse prescribing literature (Baileff, 2007; Latter et al., 2007a; Carey et al., 2009; Drennan et al., 2011). This comparison may, however, be influenced by the different authors' definitions of what constitutes a complete prescription or details of medication supplied. For example, we considered that omission of 'route of administration' constituted an error, whereas other studies may not have considered this an error if there was only one formulation of that drug. The increasing introduction of electronic prescribing within clinical areas is likely to improve prescribing governance and safety (Ahmed et al., 2016); however, this relies on the accuracy of the drug library held within the database. As seen in our study, one service consistently recorded an inaccurate metronidazole regimen within the electronic database but provided patients with correct pre-packed medication supplies in line with their local treatment policy for bacterial vaginosis.

Medication provision errors and their potential severity

The Medical Protection Society (2016) reported that medication provision errors were the second most common cause for healthcare litigation, citing contraindicated drugs (most commonly antibiotics), providing the wrong drug or selecting an incorrect dose as most frequent. Frequent dose related issues have also been reported in the prescribing literature

(Carey et al., 2008; Dornan et al., 2009; Bates et al., 2010; Avery et al., 2012; Seden et al., 2013). In contrast, the findings from this study didn't identify such errors as frequent problems. It is, however, difficult to accurately compare error rates across the different studies due to variations in both error definitions and denominators. For example, not documenting patients' past medical history, concurrent medications and allergies were not considered errors by Dornan et al. (2009) or Avery et al. (2012) as they only explored prescription errors. However, we regarded the inability to assess the potential impact of a medication on pre-existing conditions as a risk to patient safety, and thus an error in prescribing safety. Nevertheless, when compared to other literature, this study gives overall reassurance that sexual health nurses were comparable to medical counterparts in other clinical settings with regards to prescribing safety.

Nurse prescribers were statistically more likely to make 'moderate' medication provision errors, compared to patient group direction users. However, the severity of these errors was, again, predominantly linked to omitted documentation, as opposed to patients being harmed, which made accurate drug safety assessments difficult. Nevertheless, there were four occurrences of medication provision errors categorised by the research judges as potentially having a 'severe' impact on patient safety, demonstrating that on-going medication safety vigilance is indicated.

Appropriateness

We found that sexual health nurse prescribers and patient group direction users delivered clinically appropriate medications. This is in line with previous nurse prescribing research in other clinical areas that has used the Medication Appropriateness Index (Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012). The low mean Medication Appropriateness Index weighted score (0.9 out of 18) in the present study established that nurse prescribers and patient group direction users made more appropriate medication choices than in studies reported previously (Latter et al., 2012).

From the Medication Appropriateness Index's ten points of enquiry, both nurse prescribers and patient group direction users scored most appropriately on the question relating to using the most cost-efficient medication regimens. This concurs with previous research (Latter et al., 2012), and is perhaps unsurprising given that sexual health nurses work within a range of nationally determined evidence-based treatment guidelines (British Association of Sexual Health & HIV, 2016; Faculty of Sexual & Reproductive Health, 2016) and locally procured formularies. Nurse prescribers and patient group direction users also scored very highly on the components 'indication for the medication', and 'medicines effectiveness for the condition' managed. This is in line with work by Naughton et al. (2012), investigating nurse prescribing in multiple clinical specialities across eight hospitals.

In our study, there was some variability between nurse prescribers and patient group direction with regards to the categories with the most inappropriate Medication Appropriateness Index scores; however, these were not statistically different. For nurse prescribers the most frequent inappropriate category related to appropriateness of dose, correct medication directions and directions being practical, whereas, for patient group direction users this was related to drug-drug interactions, medical condition-drug interactions and correct medication directions. Similar inconsistencies amongst prescribers have been reported previously (Latter et al., 2007b; Latter et al., 2012; Naughton et al., 2012). The primary reason nurse prescribers and patient group direction users scored inappropriately on the Medication Appropriateness Index was, again, due to omitted documentation, as opposed to inappropriate practice. This demonstrates the importance of comprehensive

documentation and the limitations of using clinical records for assessing medication appropriateness.

Legislation and guidelines

From a clinical governance perspective, nurse prescribers and patient group direction users were comparable with regards to the appropriateness of delivering medications that were expected to be therapeutically beneficial, in line with local and national sexual health guidelines. However, patient group direction users were found to use patient group directions outside of their restrictions (evident in 8% of patient group direction users' medication deliveries). This has been reported previously (Williams and Knox, 2011; Black and Dawood, 2013). This consequently means that patient group directions were, at times, not used within their expected legal and governance frameworks and/ or users' scope of practice. While all instances were determined to be clinically safe, patient group direction users may not have received the necessary training and assessment required to provide specific drugs for certain presentations despite having the necessary clinical knowledge. patient group direction users, and those who govern them, should remain vigilant with regards the patient group direction documents' limitations and restrictions and endeavour to ensure individual patient group directions remain fit for purpose. Local audits and regular staff training/ updates could facilitate improvements in these areas and to ensure patient group directions are not necessarily restrictive. Overall, despite some cases where the boundaries of patient group directions were pushed, there were many more cases of appropriate, safe clinical practice by patient group direction users and nurse prescribers in line with United Kingdom legislation and sexual health guidelines.

Medications not provided

We found 101 cases where patients declined medications that were otherwise indicated (e.g. offer of vaccination, treatment as sexual contact of a sexually transmitted infection). Non-provision in these instances considered patient choice as central to the consultation, facilitated the nurse and the patient to reach shared decisions on medication choice, and was deemed appropriate for both nurse prescribers and patient group direction users. However, there were a further 25 presentations in which the treatment was indicated but not offered. These cases included presentations in which prophylactic medicines had not been offered to patients who were at recent risk of pregnancy, at high risk of sexually transmitted infections or HIV, or who could have been protected through vaccination programmes (e.g. hepatitis B). The long-term consequences of not providing medications in these circumstances could potentially lead to health outcomes that heavily impact on patients' health and are expensive to manage in the future (e.g. HIV and/ or hepatitis B).

Generalisability to other healthcare settings and systems

This study included urban tertiary level sexual health services in five separate National Health Service funded services spread throughout the United Kingdom. This allowed for maximum variability of services within the study's resources but may not represent all sexual health services, rural services or those in other countries. Nevertheless, while these findings are restricted to sexual health, it is expected they would have some generalisability to other services and specialities where patients present for discrete episodes of healthcare. Our study could provide additional reassurance to other healthcare systems and countries looking to expand medication access beyond medical staff but concerned about the safety of doing so.

Strengths and weaknesses

Clinical records

The use of clinical records allowed a large-scale review of clinical practice of nurse prescribers and patient group direction users' practice, permitting data collection consistency and standardisation across five separate sexual health services. Moreover, this method allowed these comparisons to be based on actual practice as opposed to being limited to nurses that volunteered to participate in research. Nevertheless, as demonstrated throughout, the use of clinical notes is limited by the quality of documentation. Just because aspects were not documented doesn't mean they were not considered; however, data collection using this method relies on what was documented. This method was also time consuming as it required the researcher to review a large volume of clinical records that were not relevant to the project as it was not always possible to determine which practitioner managed the patient from the services' clinic attendance lists.

Observations

The use of the observations allowed the research team to determine how nurses and patients interact during medication consultations and compare this to a prescribing framework. This is not possible through clinical notes review alone. Nevertheless, the researcher's presence likely altered the behaviours of both the nurse and patients as they knew they were being observed. The use of audio recording, as opposed to video recording, also limits the ability to assess non-verbal communication; however, audio-recording was felt to be more appropriate by the research team for sexual health consultations where patients had limited time to consider participation due to the unplanned nature of sexual health presentations.

Future research opportunities

Further exploration of medication safety and appropriateness is required across other specialities and professions, particularly as non-medical prescribing powers become widened to other healthcare professional groups and countries. This study design could be repeated in other clinical areas, specifically those areas that utilise more complex drug regimens (e.g. chemotherapy), or where patients frequently have multiple co-morbidities and/or polypharmacy. Moreover, as nurses have become independent practitioners, further research is indicated into how nurse prescribers compare with doctors' prescribing practices, and how nurses' advanced clinical skills have changed the roles of both professions. Research should also be repeated and expanded upon within different healthcare systems from countries outside the United Kingdom.

Conclusions

This study has confirmed the safety, appropriateness and professionalism that nurses have with regards to independent medication provision. However, improvements in the completeness and accuracy of clinical documentation are recommended and patient group direction users, their managers and organisational governance leads should remain vigilant regarding the restrictions associated with patient group directions in practice. Nevertheless, these findings should demonstrate to policymakers, managers and clinical staff that nurses use their medication provision powers responsibly. Exploring the safety and appropriateness

in different clinical specialties, professional groups and healthcare systems/ countries would be useful to provide additional reassurance.

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Adam Black made a substantial contribution to the conception and design of the work; the acquisition, analysis and interpretation of data and drafting the work. Molly Courtenay and Heather Gage made substantial contributions to the conception and design of the work; the analysis and interpretation of data and drafting the work. Christine Norton made a substantial contribution to the conception and design of the work, interpretation of data and critically revised drafts of the work. Bryony Dean Franklin and Trevor Murrells made contributions to analysis and interpretation of data and critically revised drafts of the work. All authors approved the final version to be published.

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Competing interests

Adam Black, Molly Courtenay, Heather Gage, Christine Norton, Trevor Murrells: None declared.

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